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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,455	12/01/2005	Shlomo Yitzchaik	YITZCHAIK4	4790
1444 7590 10/10/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER LULIS, MICHAEL P	
			ART UNIT 2824	PAPER NUMBER
			MAIL DATE 10/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,455	Applicant(s) YITZCHAIK ET AL.	
	Examiner Michael Lulis	Art Unit 2824	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/10/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>Search History</u> . |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Claim 2 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. The claim limitation "a few angstroms" encompasses distances larger than 15 angstroms, required by claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

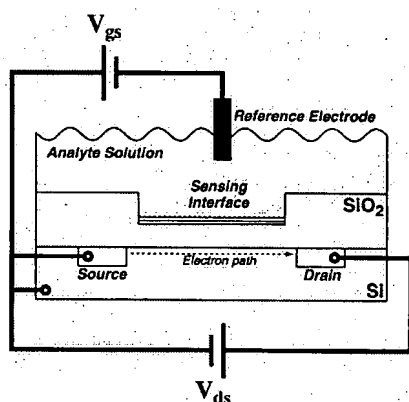
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kharitonov et al. (Sensors and Actuators B 70 (2000) pg.**

222-231) in view of Willner et al. (Agnew. Chem. Int. Ed. 39 (2000) pg. 1180-1218).

5. **Regarding claim 1**, Kharitonov et al. disclose a device (scheme 1) for the detection of analyte molecules, the device comprising at least one pair of source-drain electrodes and at least one gate electrode to thereby define at least one Field Effect Transistor (FET), wherein said at least one gate electrode is coated (scheme 3) with a layer of receptor molecules that in the presence of said analytes catalyze (section 3.1 para 1) a reaction that causes release of ions in a medium surrounding said receptor molecules, and a monolayer of linker molecules is provided for linking said receptor molecules to said at least one gate. Kharitonov et al. do not disclose expressly that a distance between the receptor molecules layer and the surface of the coated gate is smaller than 15 Å. Willner et al. disclose linker molecules that result in a distance smaller than 15 Å between an enzyme molecule layer and a surface coated by the enzyme molecule layer (fig. 2). Kharitonov et al. and Willner et al. are analogous art because they are from the same field of endeavor, chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to substitute the cyanuryl chloride linker molecule of Willner et al. for those of Kharitonov et al., resulting in a distance between the receptor molecules layer and the surface of the coated gate that is smaller than 15 Å. The reason for combining is that cyanuryl chloride is predictably useful for linking surfaces functionalized by hydroxyl groups to amino groups of lysine residues of proteins.

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Scheme 1. General configuration of the ENFET device.

Kharitonov et al. Scheme 1

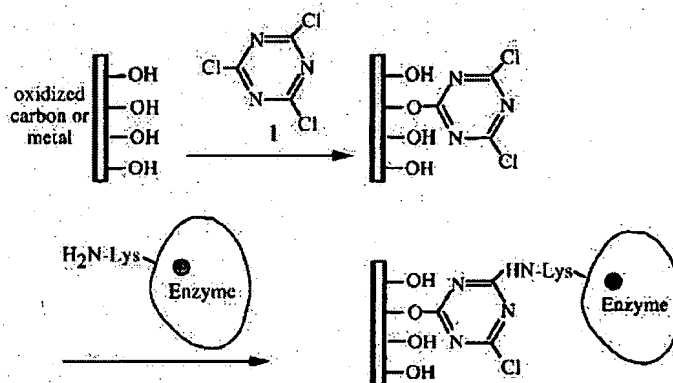
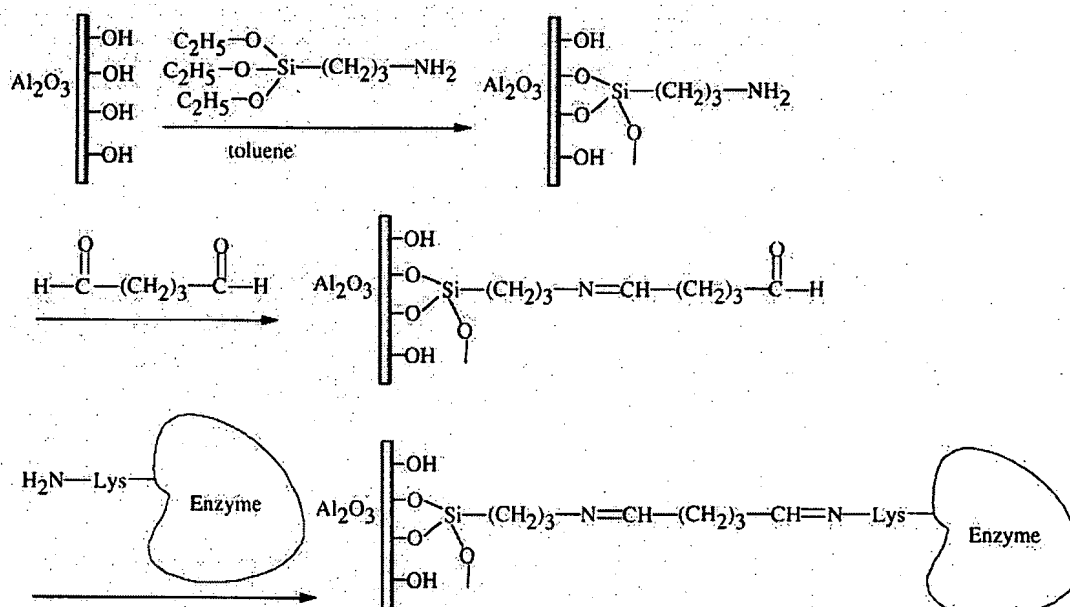


Figure 2. Assembly of enzyme-layered electrodes by the functionalization of the conductive support with cyanuryl chloride (I).

Willner et al. Figure 2



Scheme 3. Stepwise assembly of the enzyme monolayer array on the gate surface of the field-effect transistor.

Kharitonov et al. Scheme 3

6. Regarding claim 2, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 1 (see above). Kharitonov et al. do not disclose expressly that a distance between the receptor molecules layer and the surface of the coated gate is smaller than 15 Å. Willner et al. disclose linker

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molecules that result in a distance smaller than 15 Å between an enzyme molecule layer and a surface coated by the enzyme molecule layer (fig. 2). Kharitonov et al. and Willner et al. are analogous art because they are from the same field of endeavor, chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to substitute the cyanuryl chloride linker molecule of Willner et al. for those of Kharitonov et al., resulting in a distance between the receptor molecules layer and the surface of the coated gate that is smaller than 15 Å. The reason for combining is that cyanuryl chloride is predictably useful for linking surfaces functionalized by hydroxyl groups to amino groups of lysine residues of proteins.

7. **Regarding claim 3**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 1 (see above), wherein the Field Effect Transistor is an Ion Sensitive Field Effect Transistor (Kharitonov et al. section 3.1 para 1).

8. **Regarding claim 4**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 1 (see above), wherein the receptor molecules are enzymes or peptides (Kharitonov et al. scheme 3).

9. **Regarding claim 5**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 4 (see above), wherein the receptor molecules is acetylcholine esterase (Kharitonov et al. section 3.1 para 1).

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10. **Regarding claim 6**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 1 (see above), wherein said analyte molecules are selected from chemical agents used in agriculture (Kharitonov et al. cited reference 28 title), in environmental applications, industry and chemical warfare.

11. **Regarding claim 7**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 6 (see above), wherein said chemical agents are pesticides (Kharitonov et al. cited reference 28 title), herbicides, nerve agents and synthetic or natural toxins emitted from industrial plants.

12. **Regarding claim 8**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 1 (see above), wherein said gate electrode is an ion sensitive oxide gate (Kharitonov et al. section 3.1 para 1 and 2).

13. **Regarding claim 9**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 8 (see above), wherein the ion-sensitive oxide is Aluminum Oxide (Al_2O_3) (Kharitonov et al. section 3.1 para 1 and 2), Silicon Nitride (Si_3N_4), Indium Tin Oxide ($\text{In}_2\text{O}_3\text{--Sn}_2\text{O}_3$), Silicon Oxide (SiO_2) or Tantalum Oxide (Ta_2O_5).

14. **Regarding claim 10**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et

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al. to yield a device according to claim 1 (see above), wherein said linker molecules are covalently bound to at least one of the surface or the receptor molecules (Kharitonov et al. section 3.1 para 1 and 2).

15. **Regarding claim 11**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 8 (see above), wherein said linker molecules are selected from conjugated or unconjugated aliphatic, aromatic or heteroaromatic molecules (Kharitonov et al. scheme 3), having at least one functional group capable of covalently binding to said surface and at least one functional group capable of covalently binding to said receptor molecules.

16. **Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kharitonov et al. (Sensors and Actuators B 70 (2000) pg. 222-231) in view of Willner et al. (Angew. Chem. Int. Ed. 39 (2000) pg. 1180-1218) and in further view of Cho et al. (US 7013708 B1).**

17. **Regarding claim 12**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 1 (see above). Kharitonov et al. do not disclose expressly that the device comprises an array of gate electrodes each gate electrode being coated with receptor molecules layer different from that of the other gate electrodes. Cho et al. disclose an array of electrodes (fig. 12, 1220-1250), each electrode being coated with receptor molecules layer different from that of the other electrodes (column 8 lines 1-4). Kharitonov et al. and Cho et al. are analogous art because they are from the same field of endeavor,

chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to configure the gate electrodes of Kharitonov et al. in an array in which each gate electrode is coated with a receptor molecules layer different from that of the other gate electrodes. The predictable benefit of doing so would be to enable the detection of multiple analytes using a single device.

18. **Regarding claim 13**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al., Willner et al., and Cho et al. to yield a device according to claim 12 (see above). Kharitonov et al. do not disclose expressly that said array of gate electrodes is associated with the same source-drain pair. Cho et al. disclose an array of electrodes (fig. 12, 1220-1250) associated with the same source-drain pair (fig. 12, 1211 and 1212). Kharitonov et al. and Cho et al. are analogous art because they are from the same field of endeavor, chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to configure the gate electrodes of Kharitonov et al. in an array in which each gate electrode is associated with the same source-drain pair. The predictable benefit of doing so would be to enable the detection of multiple analytes using a single device.

19. **Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kharitonov et al. (Sensors and Actuators B 70 (2000) pg. 222-231) in view of Willner et al. (Angew. Chem. Int. Ed. 39 (2000) pg. 1180-1218) and in further view of Tender et al. (US 20020012937 A1).**

20. **Regarding claim 12**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al. and Willner et al. to yield a device according to claim 1 (see above). Kharitonov et al. do not disclose expressly that the device comprises an array of gate electrodes each gate electrode being coated with receptor molecules layer different from that of the other gate electrodes. Tender et al. disclose an array of electrodes (para 0032), each electrode being coated with receptor molecules layer (para 0030) different from that of the other electrodes. Kharitonov et al. and Tender et al. are analogous art because they are from the same field of endeavor, chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to configure the gate electrodes of Kharitonov et al. in an array in which each gate electrode is coated with a receptor molecules layer different from that of the other gate electrodes. The predictable benefit of doing so would be to enable the detection of multiple analytes using a single device.

21. **Regarding claim 14**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al., Willner et al., and Tender et al. to yield a device according to claim 12 (see above). Kharitonov et al. do not disclose expressly that each of the gate electrodes is associated with a different source-drain pair. Tender et al. disclose an array of electrodes (para 0032), each electrode being associated with a different source-drain pair (para 0034). Kharitonov et al. and Tender et al. are analogous art because they are from the same field of endeavor, chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to configure

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the gate electrodes of Kharitonov et al. in an array in which each gate electrode is associated with a different source-drain pair. The predictable benefit of doing so would be to enable the detection of multiple analytes using a single device.

22. **Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kharitonov et al. (Sensors and Actuators B 70 (2000) pg. 222-231) in view of Willner et al. (Angew. Chem. Int. Ed. 39 (2000) pg. 1180-1218) and in further view of Martin et al. (US 6355436 B1).**

23. **Regarding claim 15**, Kharitonov et al. disclose a method of detecting analyte molecules in a medium, the method comprising: (a) providing at least one Field Effect Transistor (FET) (scheme 1) formed by a source-drain electrode pair and at least one gate electrode that is coated (scheme 3) with a layer of receptor molecules that in the presence of certain analytes catalyze (section 3.1 para 1) a reaction that causes release of ions in a medium surrounding said receptor molecules, and a monolayer of linker molecules for linking said receptor molecules to said at least one gate, and (b) accommodating said at least one FET such that said at least one gate is exposed to a medium suspected of containing analyte molecules capable of reacting with the receptor molecules, thereby affecting a release of ions in said medium.

Kharitonov et al. do not disclose expressly that a distance between the receptor molecules layer and the surface of the coated gate is smaller than 15 Å. Willner et al. disclose linker molecules that result in a distance smaller than 15 Å between an enzyme molecule layer and a surface coated by the enzyme molecule layer (fig. 2). Kharitonov et al. and Willner et al. are analogous art

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because they are from the same field of endeavor, chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to substitute the cyanuryl chloride linker molecule of Willner et al. for those of Kharitonov et al., resulting in a distance between the receptor molecules layer and the surface of the coated gate that is smaller than 15 Å. The reason for combining is that cyanuryl chloride is predictably useful for linking surfaces functionalized by hydroxyl groups to amino groups of lysine residues of proteins.

Kharitonov et al. do not disclose expressly the step (c) monitoring a change in an electric current between the source and drain electrodes caused by the release of ions, said change being indicative of the presence of said analyte in the medium, thereby enabling measuring the analyte concentration in the medium. Martin et al. disclose a step of monitoring a change in an electric current between source and drain electrodes (column 7 lines 4-8), said change being indicative of the presence of said analyte in the medium, thereby enabling measuring the analyte concentration in the medium (column 6 line 58 to column 7 line 8 and column 13 lines 1-4). Kharitonov et al. and Tender et al. are analogous art because they are from the same field of endeavor, chemical sensors. It would have been obvious at the time of invention to a person of ordinary skill in the art to use monitoring a change in an electric current between source and drain electrodes in the method of Kharitonov et al. as indication of the presence of said analyte in the medium, thereby enabling measuring the analyte concentration in the medium. The reason for doing so would have been that

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monitoring the source-drain current is a predictable alternative to monitoring voltage.

24. **Regarding claim 16**, it would have been obvious at the time of invention to a person of ordinary skill in the art to combine Kharitonov et al., Willner et al., and Martin et al. to yield a method according to claim 15 (see above), wherein said medium is one of the following: water, sea water, buffer, and ionic solution (Kharitonov et al. section 2.3).

Conclusion

When responding to this office action, applicants are advised to provide the examiner with the line numbers and page numbers in the application and/or references cited to assist the examiner in locating appropriate paragraphs.

A shortened statutory period for response to this action is set to expire three months and zero days from the date of this letter. Failure to respond within the period for response will cause this application to become abandoned (see MPEP 710.02(b)).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Lulis whose telephone number is (571) 272-9015. The examiner can normally be reached on 8:30 AM to 5:00 PM Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Elms can be reached on (571) 272-1869. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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01 October 2007



RICHARD T. ELMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800